REMARKS

By way of summary, Claims 1–28, 37–98, 107–115, and 121–145 were pending in this application with Claims 1–28, 37–78, 84–98, and 109–115 withdrawn from consideration. By this Amendment, Claims 79, 107, 129, and 145 have been amended, and Claims 146–150 have been added. Applicants have canceled duplicate Claims 126 and have added them as new Claims 149 and 150. Applicants also respectfully note that Claim 128 was never presented, and thus, Claim 128 is omitted from the listing of claims above. This Amendment is submitted with a Request for Continued Examination. Accordingly, Claims 1–28, 37–98, 107–115, 121–125, and 127–150 are now pending.

§102(e) Rejection under Kaganov et al.

The final Office Action rejected Claims 79–83, 107–108, and 121–145 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,876,367 to Kaganov et al. Applicants respectfully submit that amended independent Claims 79, 107, 129, and 145 are not anticipated by Kaganov and that the § 102(e) rejection should be withdrawn for at least the reasons set forth below.

Kaganov

Kaganov et al. disclose methods and devices for protecting a patient from embolization during arteriotomy procedures. In particular, the reference provides a bypass tubing or indwelling shunt, having a main lumen for blood bypass and a second, branching lumen adapted to receive an elongated blood filtration instrument and to allow passage of the instrument into an artery distal to an endarterectomy region. Col. 2:3–11.

Figure 6 of Kaganov, reproduced here for reference, depicts an embodiment in which the shunt is secured to the vessel walls using one or more balloon occluders. Kaganov states, "[S]hunt 10 includes one or more balloon occluder 35 at its proximal and/or distal ends, the balloon occluder being disposed circumferentially around the tubing

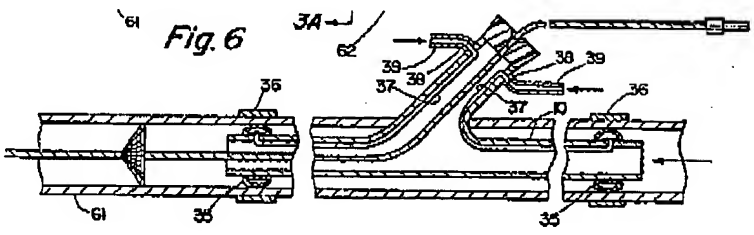

Fig. 6

of the shunt." Col. 6:16–19. Kaganov also states that a "cuff or C-clamp 36 may be fitted about the vessel to prevent hyperexpansion, minimize internal slippage of the balloon occluder, and provide a tight seal within the vessel." Col. 6:26–31.

Applicants further note the record indicates that at the time the inventions of the present application were made, the present application and the Kaganov reference were owned by, or subject to an obligation of assignment to, the same entity. In particular, the Kaganov reference was assigned to Embol-X, Inc., by an assignment executed on February 4, 1997. Likewise, the priority application of the present application, U.S. Application No. 08/852,867, filed on May 8, 1997, and ultimately issued as U.S. Patent No. 5,911,734, was assigned to Embol-X, Inc., by an assignment executed on October 21, 1997. Under 35 U.S.C. § 103(c), Kaganov is, therefore, precluded from subsequently being combined with other references in support of a § 103(a) obviousness rejection.

Independent Claim 79

Applicants respectfully submit that amended Claim 79 is not anticipated by Kaganov because the reference does not teach all the limitations of amended Claim 79. For example, Claim 79 now recites, in part, "an expandable member, coupled to the guide member, that is sized and configured to be inserted into a stenotic lumen of the blood vessel and to expand from an unexpanded dimension to an expanded dimension that is greater than the unexpanded dimension, such that the stenotic lumen of the blood vessel is less stenotic after expansion of the expandable member within the blood vessel than before the expansion."

Applicants respectfully submit that Kaganov does not teach such an expandable member. Specifically, Applicants submit that the shunt does not disclose an expandable member that is "sized and configured to be inserted into a stenotic lumen of the blood vessel" and that expands "from an unexpanded dimension to an expanded dimension . . . such that the stenotic lumen of the blood vessel is less stenotic after expansion . . . than before the expansion." For example, one embodiment of such an expandable member is the angioplasty balloon illustrated in Figure 2 of the present application, reproduced here for reference. Kaganov discloses a balloon on the shunt, but this balloon is described only in connection with its operation as an occluder to seal the vessel from blood flow. *See* Col. 6:10–31. Kaganov provides no teaching or disclosure that

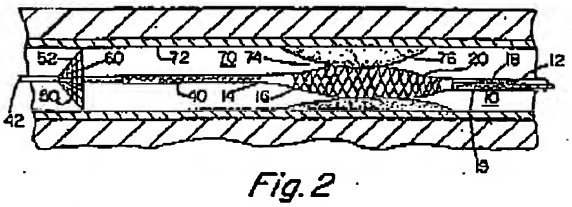

Fig. 2

the occluder 35 is sized and configured to be, or even capable of being, "inserted into a stenotic lumen of the blood vessel" and expanding "from an unexpanded dimension to an expanded dimension . . . such that the stenotic lumen of the blood vessel is less stenotic after expansion . . . than before the expansion," as recited in amended Claim 79. Accordingly, Applicants respectfully submit that Kaganov does not teach all the limitations now recited in Claim 79 and that the § 102(e) rejection of Claim 79 based on Kaganov should, therefore, be withdrawn.

Independent Claim 107

Applicants respectfully submit that amended Claim 107 is not anticipated by Kaganov because the reference does not teach all the limitations of amended Claim 107. For example, Claim 107 now recites, in part, "a balloon in communication with a balloon inflation lumen of the sleeve, the balloon being sized and configured to be inserted into a stenotic lumen of a body vessel and to expand from an unexpanded dimension to an expanded dimension that is greater than the unexpanded dimension, such that the stenotic lumen of the body vessel is less stenotic after expansion of the expandable member within the body vessel than before the expansion."

Applicants respectfully submit that Kaganov does not teach such balloon. In particular, Applicants submit that the shunt of Kaganov does not include a balloon that is "sized and configured to be inserted into a stenotic lumen of a body vessel" and that expands "from an unexpanded dimension to an expanded dimension . . . such that the stenotic lumen of the body vessel is less stenotic after expansion . . . than before the expansion." Accordingly, Applicants respectfully submit that Kaganov does not teach all the limitations now recited in Claim 107 and that the § 102(e) rejection of Claim 107 based on Kaganov should, therefore, be withdrawn.

Independent Claim 129

Applicants respectfully submit that amended Claim 129 is not anticipated by Kaganov because the reference does not teach all the limitations of amended Claim 129. For example, Claim 129 now recites, in part, "an expandable member, coupled to the introducer sheath, that is sized and configured to be inserted into the obstruction of the blood vessel and to expand from an unexpanded dimension to an expanded dimension that is greater than the unexpanded dimension, such that the blood vessel is less obstructed after expansion of the expandable member within the blood vessel than before the expansion."

As explained above, Applicants respectfully submit that Kaganov does not teach such an expandable member. In particular, Applicants submit that the shunt does not include an

expandable member that is "sized and configured to be inserted into the obstruction of the blood vessel" and that expands "from an unexpanded dimension to an expanded dimension . . . such that the body vessel is less obstructed after expansion . . . than before the expansion." Accordingly, Applicants respectfully submit that Kaganov does not teach all the limitations now recited in Claim 129 and that the § 102(e) rejection of Claim 129 based on Kaganov should, therefore, be withdrawn.

Independent Claim 145

Applicants respectfully submit that amended Claim 145 is not anticipated by Kaganov because the reference does not teach all the limitations of amended Claim 145. For example, Claim 145 now recites, in part, "an expandable member, coupled to the filter, that is sized and configured to be inserted into a stenotic lumen of a blood vessel and to expand from an unexpanded dimension to an expanded dimension that is greater than the unexpanded dimension, such that the stenotic lumen of the blood vessel is less stenotic after expansion of the expandable member within the blood vessel than before the expansion."

Applicants respectfully submit that Kaganov does not teach such an expandable member. In particular, Applicants submit that the shunt does not include an expandable member that is "sized and configured to be inserted into a stenotic lumen of a blood vessel" and that expands "from an unexpanded dimension to an expanded dimension . . . such that the stenotic lumen of the body vessel is less stenotic after expansion . . . than before the expansion." Accordingly, Applicants respectfully submit that Kaganov does not teach all the limitations now recited in Claim 145 and that the § 102(e) rejection of Claim 145 based on Kaganov should, therefore, be withdrawn.

Dependent Claims 80–83, 107–108, 121–125, 127–144, and 146–150

Claims 80–83, 107–108, 121–125, 127–144, and new Claims 146–150 depend from independent claims 79, 107, 129, and 145. Applicants respectfully submit that these dependent claims are patentable over the cited reference for at least the same reasons set forth above with respect to amended Claims 79, 107, 129, and 145, in addition to the patentable subject matter recited in each dependent claim. Accordingly, Applicants respectfully request that the § 102(e) rejection be withdrawn and that these dependent claims, as well as the newly added dependent claims, be allowed.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the cited reference shows or teaches, even if not expressly discussed herein. For purposes of this response, we have treated the cited reference as prior art, but Applicants respectfully reserve the right to challenge later whether the cited reference is prior art. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225 (RMI-5730CON6).

Respectfully submitted,

Date: July 2, 2008

Gregory J. Carlin, Reg. No. 45,607
Edwards Lifesciences Corporation
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6856
Facsimile: (949) 250-6850
Customer No. 30452